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6 April 2001

Larry D. Spears, Acting Director
Office of Compliance, Center for Devices and Radiological Health
U.S. Department of Health and Human Services
Food and Drug Administration
2098 Gaither Road (HFZ-340)
Rockville, MD 20850

Dear Mr. Spears,

The Society of Gastroenterology Nurses and Associates, Inc. (SGNA) has closely followed the issue of reuse of single use medical devices and the FDA's strategy to oversee reprocessing of these devices. SGNA has sent representatives to several FDA-sponsored meetings and formally responded to the agency's draft guidelines during the comment period.

SGNA voiced support for the classification system proposed in the draft document. However, we strongly disagree with the decision to abandon the original classification of single-use devices according to the risk of infection. Public safety is not protected when gastroenterology accessories cannot be adequately reprocessed or fail to perform acceptably as a result of the rigors of reprocessing.

Gastrointestinal endoscopy units have been targeted by third party reprocessors for the past several years. Yet under the classification system adopted in the final regulations, most gastroenterology accessories are designated Class II, and will not be subject to regulation until August 2001 or later.

Of particular concern to SGNA is the designation of biopsy forceps as Class I exempt. We urge the FDA to rethink this classification of biopsy forceps. This particular device is intended to break the mucosal barrier and thus falls into the Spaulding Classification as a critical device. Any endoscopy nurse can attest to the difficulty of cleaning biopsy forceps, even those that have 510(k) clearance as reusable devices. SGNA believes that it is imperative that the reprocessing of biopsy forceps manufactured and labeled as single use instruments receive rigorous review by the FDA. Reprocessors must provide data demonstrating the efficacy of cleaning and sterilization of biopsy forceps and verify their functionality before allowing these devices back into the marketplace. In the absence of such guidance and direction, SGNA will advise members not to reuse critical devices manufactured and labeled for single use.

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SGNA is further concerned about the FDA's decision not to extend its oversight into reprocessing of single use devices by ambulatory care centers and physicians' offices. This sets the stage for a dual standard of care that will put at risk patients receiving care in these settings versus the hospital setting. While we are mindful of the FDA's budget constraints, we are also cognizant of its mandate to protect the public health.

On behalf of its membership, which includes professional nurses, citizens and constituents, the Society of Gastroenterology Nurses and Associates urges the FDA to take these concerns into consideration in a timely manner. We ask that the FDA act to revise its Enforcement Priorities for Single Use Devices Reprocessed by Third Parties and Hospitals accordingly.

Sincerely,

Nancy Schlossberg, BA BSN RN CGRN
SGNA President

Sallie Walker, BA RN CGRN
Chair, SGNA Practice Committee

Enclosure: SGNA Position Statement, Reuse of Single Use Critical Medical Devices, 2001